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PATENT
Attorney Docket No.: 06267.0053

#12/A
8-26-02
RP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
)
Ilkka LARMA et al.)
)
Serial No.: Unassigned) Group Art Unit: Unassigned
)
Filed: Filed Herewith) Examiner: Unassigned

For: CONTROLLED RELEASE PERORAL COMPOSITIONS OF
LEVOSIMENDAN being a **National Stage filing** of PCT International
Application No. PCT/FI99/00329, filed on April 23, 1999

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Preliminary Amendment

Please amend the application as follows:

In the Specification:

Please amend the specification as follows:

Page 1, after the title, insert a first paragraph as follows:

This application is a national stage filing of PCT International Application
No. PCT/FI99/00329, filed on April 23, 1999, which published in English.

In the Claims:

Please add new claims 11-17 and amend claims 1-4 and 7-10 as follows

1. (Amended) A controlled release composition for oral administration comprising a) a therapeutically effective amount of levosimendan and b) a drug release controlling component for providing the release of levosimendan over an extended period of time and a steady-state plasma level for the levosimendan metabolite (R)-N-[4-(1,4,5,6-tetrahydro-4-methyl-6-oxo-3-pyridazinyl)phenyl]acetamide [(II)] of less than 20 ng/ml [, preferably less than 10 ng/ml].